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10/575,779	09/28/2007	Michael Teifel	062587-5007	9429
9629 7590 04082010 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW			EXAMINER	
			SCHULTZ, JAMES	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/575,779 TEIFEL ET AL. Office Action Summary Examiner Art Unit JD SCHULTZ 1633 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 December 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 36-70 is/are pending in the application. 4a) Of the above claim(s) 64-66 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 36-63 and 67-70 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date see action.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/S5/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

### DETAILED ACTION

#### Election/Restrictions

Applicant's election without traverse of Group II in the reply filed on 12/23/2009 is acknowledged. It is noted that applicants have canceled all previously pending claims 1-35, and have introduced new claims 36-70, ostensibly to cure defects in claim form. Applicants have elected the species "Cancer" in claims 51 and 67, and "chemotherapeutic agent" in claims 59 and 61-66 as the active agent.

In the restriction requirement dated July 24, 2009, applicants were required to elect a species of cancer chosen from the group consisting of pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma, rather than the generic "cancer". However, in reviewing the claim language (i.e. claim 67), it is noted that the species of cancer from which applicants were to elect (i.e. pancreatic, gastro-intestinal, etc.) were not recited as necessary elements of the claim, due to the use of the phrase "especially" in referring to be species of cancers that may be treated. Such language is interpreted as reading on the treatment of any cancer, not just those species recited in the claim. Accordingly, the election of the generic "cancer" is considered appropriate; however, any future amendment to require a particular species of cancer will also require an election of a specific species of cancer.

Applicants have also elected the generic term "chemotherapeutic agent". It is noted that there are numerous species claimed that fall under this generic scope, some such species recited as being required elements of the claim, whereas others are listed as examples or referred to as

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"especially" preferred type species. As above, any future amendment that requires a particular chemotherapeutic agent in the claims will also require the election of a specific species of chemotherapeutic agent.

Finally, applicants were required to indicate which claims are considered to read on the elected species, and indicated that claims 36-70 read on the elected species. This is not adopted. At least claims 64-66 are not considered to read on chemotherapeutic agents, and are thus withdrawn from examination is being drawn to nonelected species. Accordingly, claims 64-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 12/23/2009. Claims 36-63, and 68-70 are currently under examination.

#### Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 14, 2006 was filed before the mailing date of the instant first action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner, and a signed and initialed copy is enclosed herewith.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless

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the references have been cited by the examiner on form PTO-892, they have not been considered.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-56 61, 67, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 recites the method of claim 50, wherein the disease or condition is a wound healing, cancer, an inflammatory disease or a chronic inflammatory disease such as rheumatoid arthritis, dermatitis, psoriasis or endometriosis. Claim 52 recites a method of treating or preventing a disorder associated with and/or accompanied by occurrence of drug resistant cells, such as drug resistant tumors comprising administering to a patient in need thereof a pharmaceutical composition comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%. Claim 53 and claim 54 depend upon claim 52 and contain at least all limitations recited therein.

Claim 55 recites a method of treating or preventing metastasis formation, <u>such as</u> an onset and/or progression, particularly associated with and/or accompanied by a tumor disorder comprising administering a pharmaceutical composition comprising a cationic liposomal

preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at 1 east one neutral and/or anionic lipid from about 0 mole % to about 70 mole%. Claim 56 depends upon claim 55 and contains at least all limitations recited therein.

Claim 61 recites the method of claim 55, wherein the active agent is selected from a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, other agents interacting with microtubuli such as discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictyin A and B, and in a most preferred embodiment it is selected from paclitaxel, docetaxel, camptothecin or any derivative thereof. Claim 67 recites the method of claim 36 for the treatment of cancer, especially pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma. Claim 69 recites the method of claim 36, wherein the cationic liposomal preparation is administered systemically, preferably intravenously.

The exemplary language underlined above is considered to render the claims indefinite, since it cannot reasonably be discerned whether such limitations are actual requirements of the claims or exist in said claims merely as supporting examples. Construing reasonably broadly, and for the purpose of compact prosecution, these limitations are considered supportive material and are not required by the claim to provide novelty or nonobviousness. However, clarification is required.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim36-63 and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDonald (U. S. Patent Number 7,112,338) in view of Rahman et al. (U. S. Patent Number 6,146,659).

Claim 36 recites a method of treating a patient suffering from a disease or condition comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%. Claim 37 recites the method of claim 36, wherein the monthly dose is about 0.5 mg up to about 30 mg paclitaxel/kg body weight. Claim 38 recites the method of claim 37, wherein the monthly dose is about 1.0 mg up to about 15 mg paclitaxel/kg body weight. Claim 39 recites the method of claim 37, wherein the monthly dose is about 1 to about 7.5 mg/paclitaxel/kg body weight. Claim 40 recites the method of claim 36, wherein the monthly dose is about 20 to about 60 mg/paclitaxel/kg body weight. Claim 41 recites the method of 36, wherein administering the cationic liposomal preparation comprises administering at least once daily. Claim 42 recites the method of claim 36, wherein administering the cationic liposomal preparation comprises administering a plurality of times during a month period, and wherein each administration is

separated by an interval of between one day and 3 weeks. Claim 43 recites the method of claim 36, wherein administering the cationic liposomal preparation comprises administering (i) at least 3 times or 3-5 times in a first week, followed by an interval of 1-3 weeks without administration, and optionally one or several repeats of this protocol; (ii) once in a first week followed by an interval of at least one week or 1-3 weeks, without administration, and optionally one or several repeats of this protocol; (iii) once in a week for one week or several successive weeks; or (iv) a combination of (i), (ii) and/or (iii).

Claim 44 recites a method of treating a patient suffering from a disease or condition with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition comprising a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy. Claim 45 recites the method of claim 44, wherein the composition is administered simultaneously with an effective dose of at least one further active agent. Claim 46 recites the method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of at least about 2 mole% to about 8 mole%. Claim 47 recites the method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of about 2.5 mole% to about 3.5 mole%. Claim 48 recites the method of claim 36, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel. Claim 49 recites the method of claim 36, wherein the cationic liposomal preparation comprises substantially no paclitaxel

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crystals. Claim 50 recites the method of claim 36, wherein the condition is an angiogenesisassociated condition. Claim 51 recites the method of claim 50, wherein the disease or condition is a wound healing, cancer, an inflammatory disease or a chronic inflammatory disease such as rheumatoid arthritis, dermatitis, psoriasis or endometriosis.

Claim 52 recites a method of treating or preventing a disorder associated with and/or accompanied by occurrence of drug resistant cells, such as drug resistant tumors comprising administering to a patient in need thereof a pharmaceutical composition comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%. Claim 53 recites the method of claim 52, wherein the method is a second or third line treatment for cancer. Claim 54 recites the method of claim 52, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 55 recites a method of treating or preventing metastasis formation, such as an onset and/or progression, particularly associated with and/or accompanied by a tumor disorder comprising administering a pharmaceutical composition comprising a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%. Claim 56 recites the method of claim 55, wherein the method treats or prevents liver metastasis formation.

Claim 57 recites a method of treating a patient with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition comprising a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9

mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy against metastasis onset and/or progression, e.g. associated with and/or accompanied by the tumors. Claim 58 recites the method of claim 57, wherein the composition is administered simultaneously with an effective dose of at least one further active agent. Claim 59 recites the method of claim 52, wherein the active agent is selected from a cytotoxic or cytostatic substance such as an anti-tumor or an anti-endothelial cell active substance, a chemotherapeutic agent or an immunological active substance. Claim 60 recites the method of claim 55, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel, Claim 61 recites the method of claim 55, wherein the active agent is selected from a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, other agents interacting with microtubuli such as discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictvin A and B, and in a most preferred embodiment it is selected from paclitaxel, docetaxel, camptothecin or any derivative thereof. Claim 62 recites the method of claim 44, wherein the further active agent is an anti- endothelial cell active substance, an anti-tumor active substance, a chemotherapeutic agent, an immunological active substance, a compound that reduces or eliminates hypersensitivity reactions or a chemosensitizer. Claim 63 recites the method of claim 44, wherein the further active agent is selected from antineoplastic agents especially antimitotic agents like paclitaxel, alkylating agents especially platinum containing compounds like cisplatin, carboplatin, DNA

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topoisomerase inhibiting agents like camptothecin or doxorubicin, RNA / DNA antimetabolites, especially 5- fluorouracil or gemeitabine and other compounds having antitumor activity.

Claim 67 recites the method of claim 36 for the treatment of cancer, especially pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma. Claim 68 recites the method of claim 36, wherein the cationic liposomal preparation comprises liposomes having an average particle diameter from about 25 nm to about 500 nm, preferably about 100 nm to about 300 nm Claim 69 recites the method of claim 36, wherein the cationic liposomal preparation is administered systemically, preferably intravenously.

Claim 70 recites a method of treating a disease or condition comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 9 mg up to about 2337 mg of paclitaxel/m2 body surface of the human patient, wherein the pharmaceutical composition comprises at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

McDonald et al. teach the use of liposomally delivered paclitaxel for the purpose of treating cancer in a variety of %mole concentrations of cationic and neutral lipids that are within the range claimed instantly including the specifically claimed 50:47:3 ratio of DOTAP/DOPC/paclitaxel (see paragraph 82 and on, particularly paragraph 87 for example). McDonald teach the use of a variety of additional inhibitors of angiogenesis and chemotherapeutics that are to be used in conjunction with the paclitaxel liposomes of McDonald et al., and that such treatments constitute at least a second line of treatment (para. 93 for

example). McDonald teach using paclitaxel in combination with other chemotherapeutics (para.

9). McDonald also teach such liposomes having a particle diameter that overlaps almost exclusively with the instant patent claims (Para. 64 for example).

McDonald do not teach the dosing frequency (i.e. daily, monthly etc) and the instantly claimed mg/kg body weight of paclitaxel, although paragraph 102 of McDonald states that

"The amount of angiogenic inhibitor or promoter will depend upon the size, age, sex, weight, and condition of the patient as well as the potency of the substance being administered. Having indicated that there is considerable variability in terms of dosing, it is believed that those skilled in the art can, using the present disclosure, readily determine appropriate dosing by first administering extremely small amounts and incrementally increasing the dose until the desired results are obtained. Although the amount of the dose will vary greatly based on factors as described above, in general, the present invention makes it possible to administer substantially smaller amounts of any substance as compared with delivery systems which target the surrounding tissue e.g., target the tumor cells themselves.

Rahman et al. teach dosing ranges for liposomally encapsulated paclitaxel and teaches dosing may take place daily, weekly or monthly, and for how long.

It would have been obvious to one of ordinary skill in the art to develop a dosing regimen using the liposomal formulations of McDonald, which are identical to those claimed, but experimenting in a manner suggested by both McDonald and Rahman to achieve the instantly claimed schedules and doses. In the absence of evidence to the contrary, one of ordinary skill in the art would have to do no more than perform routine optimization of the regimens taught by the cited prior art to arrive at the instantly claimed invention. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)". (see M.P.E.P. 2144.05). Accordingly, in the absence of evidence to the contrary, one of

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ordinary skill in the art would have considered the claimed invention to have been prima facie obvious at the time of filing.

## Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignces. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 645 (CCPA 1962).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36-63, and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11, 14, 18, and 20 of copending Application No. 11/018,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because the competing claims are drawn to methods of making the liposomes of the instant claims. Since the competing claims describe methods of making these compounds, and since In Re Ochiai states that a given compounds renders its

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methods of making and using obvious, the instant claims are considered to be patentably indistinct from the competing claims.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 36-63, and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13, 16, and 22 of copending Application No. 12/300,448. Although the conflicting claims are not identical, they are not patentably distinct from each other because the competing claims are drawn to methods of treatment using the liposomes of the instant claims. The instant claims are considered to be patentably indistinct from the competing claims because the competing claims are broader, particularly in that the competing claims don't recite treatment and dosing regimens. However, these are considered to be obvious in view of the prior art as described above, and the competing claims are accordingly considered to be patentably indistinguishable.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 36-63, and 67-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 5 and 9 of copending Application No. 12/308,748. Although the conflicting claims are not identical, they are not patentably distinct from each other because the competing claims are drawn to methods of treatment using the liposomes of the instant claims. The instant claims are considered to be

patentably indistinct from the competing claims because the competing claims are broader,

particularly in that the competing claims don't recite treatment and dosing regimens. However,

these are considered to be obvious in view of the prior art as described above, and the competing claims are accordingly considered to be patentably indistinguishable.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Conclusion

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (foll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides

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Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/JD SCHULTZ/ Primary Examiner, Art Unit 1633